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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,952

10/04/2004

Reddy Bandi Parthasaradhi

H1089/20015

3097

3000 7590 05/21/2009
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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

05/21/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/509,952	PARTHASARADHI ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Response filed by applicants dated Feb. 12, 2009 have been entered and considered carefully.

Claims 1-4 are pending.

2. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using solvents of methanol/ethanol:CHCl₃ in 1.2-1 v/v, does not reasonably provide enablement for the claimed scope of unlimited combination of alcohol selected from the group consisting of methanol, ethanol, isopropyl alcohol, tert-butyl alcohol and n-butyl alcohol and the chlorinated solvent selected from the group consisting of chloroform, methylene dichloride, carbontetrachloride and ethylene dichloride with any and all ratio. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the invention commensurate in scope with these claims.

It is noted that optimization of solvent evaporation is an unpredictable parameter in experimentation of spray drying process in production (see O'Hara et al. factorial experimental design). The specification provided operability with methanol/ethanol to CHCl₃ in a 1.2-1 ratio does not offer sufficient evidence that the scope of such variation of unlimited combination of alcohol selected from the group consisting of methanol, ethanol, isopropyl alcohol, tert-butyl alcohol and n-butyl alcohol and the chlorinated solvent selected from the group consisting of chloroform, methylene dichloride, carbontetrachloride and ethylene dichloride with any and all ratio could be employed to produce the product with the same amorphous material.

3. The rejection of claims 1 and 4 under 35 USC 102(e) over Vidyadhar et al. is maintained for reason of record.

Applicants argued that the prior art does not anticipate because it does not inherently contain applicants' "mixture". This is erroneous with respect to claims 1 or 4 because no limitation was found in the claims. Applicants provided no evidence that the residue MeCl₂ in MeOH formed in situ in the prior art has any difference between a mixture of adding the two

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solvent. The CRC handbook and '842 references provided factual varification that indeed the inherent nature was found.

4. The rejections of claims 1-4 over Vijyadhard '765 in view of Imai '864 or over Sugimoto '841 or Vijyadhard '765 or Imai '864 in view of Lieberman and Brittain are maintained for reasons of record.

It is unclear what was the basis of applicants' argument in so far as the "elements taught or suggested" by the prior art. Please note that in so far as the scope of the claims are concerned, the picking and choosing from the *conventional* well known solvents taught in the prior art modifying a proven process of making donepezil hydrochloride amorphous form is prima facie obvious since such solvents were demonstrated to dissolve donepezil hydrochloride in the prior art and conventionally available in operations such as spray/vacuum drying. If applicants' argument is that a specific combination of methanol/ethanol to CHCl_3 in ratio of 1.2-1 which gives optimum operability in solvent evaporation processes and which is not found in the prior art, then, currently, a requirement of such an element was not found in the claims. Therefore, there is no basis or description supporting the argument and the rejection is proper and maintained.

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
May 7m 2009

*/Celia Chang/
Primary Examiner
Art Unit 1625*